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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/619,649	03/27/1996	RADOJE DRMANAC	ARCD:146/BOW	7575

7590 04/02/2007  
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EXAMINER
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FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 08/619,649	<b>Applicant(s)</b> DRMANAC, RADOJE	
	<b>Examiner</b> BJ Forman	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 97 and 157-176 is/are pending in the application.
- 4a) Of the above claim(s) 176 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 97 and 157-175 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 16 June 02006 in which the title was changed and claims 97, 160, 166, 170 were amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 14 March 2006 under 35 U.S.C. 112, first paragraph are withdrawn in view of Applicant's comments on pages 6-7 of the response. The previous rejections under 35 U.S.C. 102(b and e) and 35 U.S.C. 103(a), not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 97, 157-175 are under prosecution.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 97, 159-160, 163-166, 169-170 and 173-175 are rejected under 35 U.S.C. 102(b) as being anticipated by Southern et al (Genomics, 1992, 13: 1008-1017).

Regarding Claim 97, Southern et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (Fig. 3, figure legend, line 1).

Regarding Claim 159, Southern et al disclose the support wherein the microchips are arranged in multiple rows and columns (i.e. two rows and two columns, Fig. 3).

Regarding Claim 160, Southern et al disclose the support wherein the microchips are positioned for use with a multichannel pipet (Fig. 3). The arrays of Southern are arranged in two rows of two columns. While Southern does not teach use of a multichannel pipet, the courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Southern teaches the structural elements of the claim and therefore, anticipates the support of Claim 160.

Regarding Claim 163, Southern et al disclose the support wherein the array of microchips comprises more than 256 probes i.e. each of the four microchips has 256 probes. Hence, the support of Claim 97 has more than 256 probes per array as claimed.

Regarding Claim 164, Southern et al disclose the support wherein the probes are between 4 and 9 bases (Fig. 3).

Regarding Claim 165, Southern et al disclose the support wherein the probes are synthesized on the support (page 1009, left column). Southern et al do not teach light-directed synthesis. However, the courts have stated that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the

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prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. Because determination of patentability is based on the product and because Southern et al teach the product, the process of making the product as recited in the claim does not define the product over that of Southern.

Regarding Claim 166, Southern et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (Fig. 3, figure legend, line 1).

Regarding Claim 169, Southern et al disclose the support wherein the microchips are arranged in multiple rows and columns (i.e. two rows and two columns, Fig. 3).

Regarding Claim 170, Southern et al disclose the support wherein the microchips are positioned for use with a multichannel pipet (Fig. 3). The arrays of Southern are arranged in two rows of two columns. While Southern does not teach use of a multichannel pipet, the courts have stated that a claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Southern teaches the structural elements of the claim and therefore, anticipates the support of Claim 160.

Regarding Claim 173, Southern et al disclose the support wherein the array of microchips comprises more than 256 probes i.e. each of the four microchips has 256 probes. Hence, the support of Claim 97 has more than 256 probes per array as claimed.

Regarding Claim 174, Southern et al disclose the support wherein the probes are between 4 and 9 bases (Fig. 3).

Regarding Claim 175, Southern et al disclose the support wherein the probes are synthesized on the support (page 1009, left column). Southern et al do not teach light-directed synthesis. However, the courts have stated that “even though product-by-process

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claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. Because determination of patentability is based on the product and because Southern et al teach the product, the process of making the product as recited in the claim does not define the product over that of Southern.

#### **Response to Arguments**

4. Applicant asserts that Southern does not teach the four copies of the arrays are physically separated as newly claimed. The assertion is noted. However, as Applicant notes Southern teaches each array is in one of four quadrants on the surface (Fig. 3). The instant claims merely require that the arrays are physically separated. The four-quadrant arrangement is encompassed by the physical separation because a quadrant defines a physical location of the surface. Assignment of an array to a quadrant defines a boundary between quadrants, the boundary being the point of physical separation. In other words, if the arrays are not physically separated, they cannot be in different quadrants. Because the reference specifically teaches quadrants for each array, the arrays are physically separated by the quadrant boundary.

Applicant further points to the instant specification wherein a solution to a problem in the art is solved by providing a groove between the arrays. The citation is noted. However, the instant claims merely require a physical separation, not a groove. Therefore the arguments are not commensurate in scope with the claims. As stated above, Southern teaches the physical separation as claimed.

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5. Claims 97, 157-160, 163-170 and 173-175 are rejected under 35 U.S.C. 102(e) as being anticipated by Winkler et al (U.S. Patent No. 5,677,195, filed 20 November 1992).

Regarding Claim 97, Winkler et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (i.e. the support comprises an array of regions (#1004) wherein each region comprises an array (i.e. plurality) of probes immobilized thereon (Column 7, lines 10-41; Column 16, lines 22-53; and Fig. 12). Winkler et al define the region as having a predominate species of probe (Column 7, lines 31-38). In other words, the region has an array of probes immobilized thereon as recited in the instant claims.

Regarding Claim 157, Winkler et al disclose the support wherein the microchips are separated by physical barriers (Column 22, lines 8-14).

Regarding Claim 158, Winkler et al disclose the support wherein the microchips are separated by hydrophobic surface (Column 22, lines 8-14).

Regarding Claim 159, Winkler et al disclose the support wherein the microchips are arranged in multiple rows and columns (Fig. 12).

Regarding Claim 160, Winkler et al disclose the support wherein the microchips are positioned for use with a multichannel pipet (Column 18, lines 20-37 and Column 20, lines 34-40).

Regarding Claim 163, Winkler et al disclose the support wherein the array of microchips comprises more than 256 probes i.e. more than 256 regions (Column 17, lines 49-53).

Regarding Claim 164, Winkler et al disclose the support wherein the probes are between 4 and 9 bases (Column 17, lines 55-57).

Regarding Claim 165, Winkler et al disclose the support wherein the probes are synthesized on the support via light-directed synthesis (Abstract).

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Regarding Claim 166, Winkler et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (i.e. the support comprises an array of regions (#1004) wherein each region comprises an array (i.e. plurality) of probes immobilized thereon (Column 7, lines 10-41; Column 16, lines 22-53; and Fig. 12). Winkler et al define the region as having a predominate species of probe (Column 7, lines 31-38). In other words, the region has an array of probes immobilized thereon as recited in the instant claims.

Regarding Claim 167, Winkler et al disclose the support wherein the microchips are separated by physical barriers (Column 22, lines 8-14).

Regarding Claim 168, Winkler et al disclose the support wherein the microchips are separated by hydrophobic surface (Column 22, lines 8-14).

Regarding Claim 169, Winkler et al disclose the support wherein the microchips are arranged in multiple rows and columns (Fig. 12).

Regarding Claim 170, Winkler et al disclose the support wherein the microchips are positioned for use with a multichannel pipet (Column 18, lines 20-37 and Column 20, lines 34-40).

Regarding Claim 173, Winkler et al disclose the support wherein the array of microchips comprises more than 256 probes i.e. more than 256 regions (Column 17, lines 49-53).

Regarding Claim 174, Winkler et al disclose the support wherein the probes are between 4 and 9 bases (Column 17, lines 55-57).

Regarding Claim 175, Winkler et al disclose the support wherein the probes are synthesized on the support via light-directed synthesis (Abstract).

#### **Response to Arguments**

6. Applicant asserts that the individual regions of Winkler et al have "substantially pure polymer species". Applicant further asserts that the array of regions taught by Winkler differs



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from the instantly claimed support having an array of microchips as defined by the instant specification wherein 4096 oligos having distinct sequences are arrayed on a chip, 4096 chips are produced and then arrayed.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. 4096 oligos having distinct sequences are arrayed on a chip, 4096 chips are produced and then arrayed) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is noted that the instant claims do not require that the oligonucleotide probes differ and do not require any specific number of probes. The claims merely require "an array of oligonucleotide probes". Furthermore, it is noted that the passage cited from the specification is "one exemplary embodiment" and therefore does not define and/or limit the invention.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 162 and 172 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler et al (U.S. Patent No. 5,677,195, filed 20 November 1992) in view of Augenlicht (U.S. Patent No. 4,981,783, issued 1 January 1991).

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Regarding Claims 162 and 172, Winkler et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (i.e. the support comprises an array of regions (#1004) wherein each region comprises an array (i.e. plurality) of probes immobilized thereon (Column 7, lines 10-41; Column 16, lines 22-53; and Fig. 12). Winkler et al define the region as having a predominate species of probe (Column 7, lines 31-38). In other words, the region has an array of probes immobilized thereon as recited in the instant claims.

Winkler et al further teach the support is produced using a conventional pipetting instrument (Column 20, lines 34-40) but they are silent regarding an 8 by 12 format. However, Augenlicht teach pipetting instruments wherein the preferred instruments produce an 8 by 12 pattern (Column 13, lines 55-60). Augenlicht further teach these instruments are preferred because they are automated and produce precisely defined positions. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the 8 by 12 format of Augenlicht to the arrays of Winkler et al for the expected benefit of providing precisely defined regions as desired in the art (Augenlicht, Column 13, lines 55-60).

#### **Response to Arguments**

9. Applicant reiterates the arguments presented above regarding Winkler. Applicant further argues that Augenlicht cannot cure the deficiencies of Winkler. The argument has been considered but is not found persuasive for the reasons discussed above regarding Winkler.

10. Claims 161 and 171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler et al (U.S. Patent No. 5,677,195, filed 20 November 1992) in view of Stratagene, 1988, page 39).

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Regarding Claims 161 and 171, Winkler et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (i.e. the support comprises an array of regions (#1004) wherein each region comprises an array (i.e. plurality) of probes immobilized thereon (Column 7, lines 10-41; Column 16, lines 22-53; and Fig. 12). Winkler et al define the region as having a predominate species of probe (Column 7, lines 31-38). In other words, the region has an array of probes immobilized thereon as recited in the instant claims.

Winkler et al further teach the array is used with labeled probes and buffers for hybridization analysis (Column 25, lines 6-30) but they are silent regarding the array and hybridization components combined into a kit format.

However, Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method of Winkler et al into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. 2) The other service provided in a kit is quality control" (page 39, column 1).

#### **Response to Arguments**

11. Applicant reiterates the arguments presented above regarding Winkler. Applicant further argues that Stratagene cannot cure the deficiencies of Winkler. The argument has been considered but is not found persuasive for the reasons discussed above regarding Winkler.

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**Double Patenting**

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 97 and 157-175 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,383,742.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an array of arrays. The claim sets merely differ in the arrangement of limitations within the claim sets. For example, instant claim 97 is drawn to an array of arrays while patent claims 6-8 define the array of Claim 1 as having a plurality of array. Therefore, the claim sets are not patentably distinct.

**Response to Comments**

14. Applicant acknowledges the above rejection and states that the rejection will be addressed upon indication of allowable subject matter. Applicant's acknowledgement is noted, however, the above rejection is not a provisional rejection. Because Applicant has not traversed the rejection, the rejection is made Final.

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15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### **Conclusion**

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

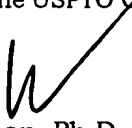
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic

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Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
March 28, 2007